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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/646,963	08/22/2003	David G. Kuehr-McLaren	5577-268	3024

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MYERS BIGEL SIBLEY & SAJOVEC
PO BOX 37428
RALEIGH, NC 27627

EXAMINER	
LE, THIEN MINH	

ART UNIT	PAPER NUMBER
2876	

DATE MAILED: 07/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/646,963	KUEHR-MCLAREN ET AL.	
	Examiner	Art Unit	
	Thien M. Le	2876	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-41 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-25 and 31-41 is/are rejected.

7)☒ Claim(s) 26-30 is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on 25 August 2003 is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 8/2003.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The information disclosure statement filed on 8/25/2003 has been entered.

Claims 1-41 are presented for examination.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1, 3-25 and 31-41 are rejected under 35 U.S.C. 103(e) as being anticipatedover Hickle et al. (Patent Publication No. 2002/0188259 A1 – Hickle et al.; herein after referred to as "Hickle").

Regarding claims 1, 6, 31, 35, and 38-41,Hickle discloses "systems for providing medical treatment, that are associated with smart supplies. The smart supplies are tagged with data carriers which may encode such information as a unique ID for the supply or component, the identification of the supply or component, the identification of the source of the supply or component, the status of whether said supply or component has been previously used, the expiration date of the supply or component, and in the case where the supply or component contains drug, the purity levels of the drug and the concentration levels of the drug. The capital equipment units or their users then utilize the information to assure quality of any procedure run with the units, by way

of improved pre-use checks, certification of the supplies for use, record keeping, inventory control, and charge capture." (see abstract)

In the summary of the invention, Hickle discloses that "despite the best quality assurance efforts of manufacturers, contaminated or defective products sometimes reach the marketplace. Ensuing product recalls are an extremely costly endeavor for the manufacturer. An identification system that would facilitate localization and removal of every single recalled product would be advantageous. As an added safety measure, it would be beneficial if the batch number and unique identification numbers of the recalled products could be programmed into the associated delivery device, like a conscious sedation machine, or at any dispensing location

like a pharmacy or a centralized database so that any recalled product, such as a tainted drug vial, slipping through the recall is rejected by the delivery device." (paragraph no. 008)

Accordingly, Hickle discloses the use of an electronic memory such as RFID tags, EEPROMS, etc. for storing information including batch information of each product (paragraph 28). Figure 1 shows a RFID tag 10 attached to a thin backing 14 that is made of a material, such as a self-adhesive paper, that can be torn by hand. The RFID tag 10 consists of a miniature integrated circuit 19, an antenna 12, a conductive loop 16, integrated circuit 19, conductive traces and pads 18. (paragraph no. 29)

Figure 3 of Hickle shows a "label 36 (the label comprising an RFID tag) identifying the contents of a syringe 28 (where the syringe is an example of an item that may be tagged according to the present invention). To identify the identity and concentration of drugs manually administered via syringe, a read-write or read-only RFID tag may be incorporated into self-adhesive, color-coded labels currently used to identify drugs in different syringes. The color-coded labels are affixed to each syringe immediately after drawing each drug, per current clinical practice. The RFID tag has encoded thereon data such as drug identity, concentration, syringe size, a unique ID or batch number, as well as use status of the tagged syringe." (see descriptions of figure 3)

Hickle further discloses that "The list of unique identification numbers and/or batch numbers of the recalled products could be downloaded from the Internet or Web to the medical device system to provide worldwide, quasi-instantaneous and timely dissemination of specific

information regarding recalled products, as the information is being updated at a manufacturer's or regulatory agency's web site. The tag may also include among its stored data an address such as a Universal Resource Locator (URL) where updated information about a tagged product such as recall status and newly discovered data such as contra-indications (not to be used with certain drugs, patients, environments or conditions). " (see paragraph no. 32)

As can bee seen, Hickle disclose a method of recalling products using batch identification numbers, delivery services systems, and the Internet which thus would meet all limitation set forth in this claim.

Regarding claim 3, see the discussions regarding claim 1. Further, Hickle disclose the method of electronically monitoring the status of the product using it tagged information (see paragraphs 32, 46) and thus would embrace all limitations set forth in this claim.

Regarding claims 4-5, see the discussions regarding claim 1. Further, the tags are recorded by one or more manufacturers, vendors (see paragraph 8) which would embrace all limitations set forth in this claim.

Regarding claims 7-14, see the discussions regarding claims 1 and 6. It is also noted that Hickle also discloses the method of requesting status of the recalls, status of the tag, at the local stores, trusted delivery services places such as pharmacies, stock rooms, central database, etc., and thus would embrace all limitations set forth in these claims.

Regarding claims 15-20, see the discussions regarding claims 1 and 6. The claims also recite various authorization level for batch recall status, including signature

of an inspecting authority, certification of an entrusted entity, etc. It is noted that Hickle discloses the method of performing recalled products utilizing delivery services systems, etc. Hickle also discloses that the manufactures of the products authorized the recalls (paragraph 13), regulation authority authorized the recalls (see paragraph 61) which thus would embrace all limitations set forth in these claims.

Regarding claims 20-22 and 36-37, Hickle discusses the use of the tags for labeling "medical devices, system components, disposables, consumables, or other products" which would embrace a consumer applicant, product features as recited in these claims (paragraph no. 15).

Regarding claims 23-25 and 32-34, the limitations of these claims have been discussions above. Hickle further discloses the use of his tags for identifying consumable products which would embrace food and drink based products.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 2 is rejected under 35 U.S.C. 103(e) as being anticipatedover Hickle et al. (Patent Publication No. 2002/0188259 A1 – Hickle et al.; herein after referred to as "Hickle") in view of Cobb et al. (Patent Publication No. 2002/0087362 - Cobb et al.; herein after referred to as "Cobb").

Regarding claim 2, see the discussions regarding claim 1. The claim differs in calling for the use of bar codes rather than RFID encoded label.

It would have been obvious to replace implement the use of bar codes in the system as taught by Hickle. The modification is merely a substitution of an art recognized equivalent which is welll within the skill levels and expectations of an ordinary skilled artisan.

Specifically, reference to Cobb is cited as an evidence showing the interchangeability of the use of either electronic memories, magnetic strip or barcodes

for storing batch identification numbers. Specifically, Cobb discloses "a medical tracking method is provided that includes attaching a machine-readable communications device, such as a bar code sticker, magnetic strip, or microprocessor chip, to a medical product, e.g., to its container, delivery device, or packaging at the time of manufacture and before shipping from the manufacturer's location. The machine-readable communications devices include encoded product data including product identification, lot or batch number, product expiration date, dosage, adverse reaction warnings, and/or other data, as appropriate." (paragraph no. 10)

Allowable Subject Matter

Claims 26-30 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The following is a statement of reasons for the indication of allowable subject matter: The prior art disclose system and method for recalling products using batch number identification, delivery systems, etc. However, the prior art fail to disclose the combination of such systems with brand loyalty card, the steps and method scanning receipts, etc., as collectively recited in claims 26-30.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thien M. Le whose telephone number is (571) 272-

2396. The examiner can normally be reached on Monday - Friday from 7:30am - 4:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Lee can be reached on (571) 272-2398. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Thien Le
Primary Examiner
Art Unit 2876
June 22, 2005